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| 10/540,551 | 10/11/2005 | Frank Mattner | 273846US0PCT | 5354 |

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| EXAMINER |
|---|
| HEARD, THOMAS SWEENEY |

| ART UNIT | PAPER NUMBER |
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| 1654 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/540,551 | MATTNER, FRANK | |
| | Examiner | Art Unit | |
| | THOMAS S. HEARD | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33,35-40,43-45 and 50-75* is/are pending in the application.

4a) Of the above claim(s) *45,50-72,74 and 75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33, 35-40, 43, 44, and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Applicants Amendments to the claims received on 4/24/2009 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 10/30/2008 are hereby withdrawn.

Claim(s) 33, 35,-40, 43, 44, 45, and 50-75 are pending. Applicants have amended claim(s) 33, 35, 45, 50-75. Claims 45, and Claims 50-72, 74, and 75 are withdrawn. Claim 45 is withdrawn as being drawn to non-elected subject matter, a method of treatment. Claims 50-72, 74, and 75 are withdrawn from consideration as the invention is under election of species practice, and the elected species has not been found free of the prior art. All other species are withdrawn until prior art issues have been resolved. Claims 33, 35-40, 43, 44, and 73 are hereby examined on the merits.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

For the purpose of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. V. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held in accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976);In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

Claims 33, 35, 36, 38, 43, 44 and the new claim 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Homburger et al., US 6,703,491 B1.

The instant invention is drawn to Applicant's elected species of SWEFRT (SEQ ID NO:113). The language of Claim 33 is open language, i.e., an isolated and purified compound which comprises the sequence selected from Applicant's elected species of SWEFRT (SEQ ID NO:113).

Homburger et al teaches the following sequence: RN 669135-91-5 REGISTRY; CN Protein (Drosophila melanogaster clone US6703491-SEQID-32985 fragment) (9CI) (CA INDEX NAME).

OTHER NAMES: CN 985: PN: US6703491 SEQID: 32985 claimed protein

SEQ 1 PEELYIDQSS QQSDRDFVEA QVPKGDKLKL HFKVNVEEQKIL**SWEFRT**FD

51 YDIKFGIYSV DDKTGEKRSE VPLGTVYSNE MDEIGYISTR PNTTYTVVFD

101 NSASYLRSKK LRYWVDLISE EEEGISELTT QMDNTQ.

The sequence in bold and underlined is the hexamer sequence of SEQ ID NO:113, instantly claimed. It is covalently attached to peptide on either side of the peptide, readable upon Claim 35 and 36, and stored and isolated in pharmaceutically acceptable buffers and salts, as taught by Homberger et al below, readable upon Claim 38. Because the purification protocols result in optimal concentrations or desired concentrations. the concentrations of Claims 43 and 44 are art recognized results effective variables. Homburger et al further teaches vectors and host cells comprising such nucleic acid SEQ ID NOs, as well as methods for the production of a Drosophila proteins (e.g., by recombinant means), and derivatives and analogs thereof. Chimeric polypeptide molecules comprising polypeptides of the invention fused to heterologous polypeptide sequences are provided. Methods to identify the biological function of a Drosophila gene are provided, including various methods for the functional modification (e.g., overexpression, underexpression, mutation, knock-out) of one gene, or of two or more genes simultaneously. Methods to identify a Drosophila gene which modifies the function of, and/or functions in a downstream pathway from, another gene are provided. The invention further provides for use of Drosophila proteins as media additives or pesticides.

It would have been obvious to one of ordinary skill in the art to clone SEQ ID NO 113 as taught by Homburger et al. One would have been motivated to do so given the expressed teaching of Homberger et al supra, where the methods are provided to make

and use SEQ ID NO 113. One would have had a reasonable expectation of success in cloning and producing SEQ ID NO 113, given Homberger's teaching of practical and known methods in the art to express and analyze the proteins from Drosophila proteins, thereby reading on isolated and purified of Claim 33. From the teachings of the references supra, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, and the invention as claimed, is rejected under 35 U.S.C. 103(a).

### ***Applicant's Arguments***

Applicants have argued the following for all of the rejections set forth in the previous office action mailed 10/30/2008:

"First and notably absent from every rejection as well as the art cited is teachings relevant to the limitation that was presented in the claims before and that remains in the claims now: "wherein said compound binds to an antibody specific for DAEFRH (SEQ ID NO: 1), but wherein $X_1X_2X_3X_4X_5X_6$ is not DAEFRH (SEQ ID NO: 1)." While Applicants understand that, during the prosecution of an application in the Office, claims are to be given their broadest reasonable interpretation consistent with the teaching in the specification (In re Bond, 710 F.2d 831,833 (Fed. Cir. 1990)), it is error to disregard express limitations in the claims. Nonetheless, as acknowledged by the Office in the rejections the art cited does not describe or fairly suggest the limitations of Claims 33 (see rejections of Eichler and Abadie) and the limitations of Claim 34 (see rejection of Bomburger). Therefore, the combination of Claims 33, 34 with Claim 30 as now presented in Claim 33 is not described or suggested by these citations."

***Response to Applicants Arguments***

Applicants arguments have been carefully considered but are not deemed persuasive to overcome the rejection. The alleged error is that the limitation of "wherein said compound binds to an antibody specific for DAEFRH (SEQ ID NO: 1), but wherein $X_1X_2X_3X_4X_5X_6$ is not DAEFRH (SEQ ID NO: 1)," was ignored. The limitation for the peptide to be 5 to 15 aino acids in length was not a limitation for the elected species, bit is now as amended. The peptide found in the prior art was not DAEFRH (SEQ ID NO: 1), so the limitation was not ignored, and the Claim 34 was not included in the 103(a) rejection. Since the peptide sequence was found, was claimed in open language (comprising), it logically follows that the compound would bind the antibody specific for DAEFRH.

It is also argued that the prior art does not describe or fairly suggest the limitations of Claim 33, but since there were no reasons set forth beyond, a blank statement, the rejection is maintained for the reasons set forth supra, as the rejection does describe why it reads on the elected species of Claim 33. Therefore, the rejection is maintained.

Claims 37, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Homburger et al., US 6,703,491 B1 in view of Abadie et al, "Specific and total IgE responses to antigenic stimuli in Brown-Norway, Lewis and Sprague-Dawley rats," Immunology (1980), Vol. 39 561-569, made of record in the previous office action, and Bergstrom et al US Patent 6,083,722.

The reference of Homburger et al., US 6,703,491 B1 have been discusses supra with respect to their motivation to combine and reasonable expectation of success in producing the instantly claimed protein.

It would have been obvious to one of ordinary skill in the art to produce an composition for making an antibody of the instantly claimed peptide as taught by Abadie et al and Bergstrom et al. One would have been motivated to make the antibodies for the peptides as such can be used in assays to detect the presence of the protein in isolates. One would have had a reasonable expectation of success in making the antibody as Abadie et al and Bergstrom et al teaches the used of aluminum hydroxide, KLH (keyhole limpet hemocyanin), or serum albumin as an adjuvant added to the peptide composition, and Bergstrom et al teaches KLH (keyhole limpet hemocyanin) or serum albumin as covalent additions to the peptide in order to enhance immunogenicity, see paragraph [125], readable on Claims 36, 38, 39, and 40. The use of an adjuvant in the manufacture of antibodies is well known in the prior art and is subject to routine optimization for the amounts of the adjuvant additives and how they are used, covalently or non-covalently. From the teachings of the references supra, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, and the invention as claimed, is rejected under 35 U.S.C. 103(a).

## New Grounds of Rejection

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 35-40, 43, 44, and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 33, the new amendments state an isolated and purified compound which comprises a sequence selected from the group consisting of SEQ ID NO:91....SEQ ID NO:115, ....and wherein the compound consists of 5 to 15 amino acid residues.

While there are peptide 5 amino acids in length in the listed peptides, the mixing of the language of “a” sequence from the group in addition to closed language of 5 to 15 amino acid residues makes the claim unclear. Further, a sequence from “a” list also makes what is being claimed unclear because “a” sequence could be any di-peptide, tri-peptide, etc… from any peptide in the list of SEQ ID NOs. The Claims prior to amendment were “the” sequence lends more clarity to the claimed subject matter.

## Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art contained in the reference of record can be applied in the next office action.**

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas S. Heard** whose telephone number is **(571) 272-2064**. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Thomas S Heard/
Examiner, Art Unit 1654